Philips FM-2 Portable Antepartum Fetal Monitor

Features



- Lightweight and portable, with carrying handle.
- Easy to read display for viewing of FHR and Toco traces and numerics.
- On-screen scrolling for viewing stored fetal traces.
- 15 BPM separated grid lines for easy viewing of fetal heart rate accelerations for NST assessment.
- Twins ultrasound monitoring capability.
- Configurable audible and flashing fetal heart rate alarms.
- Uses watertight transducers compatible with entire Series 50 range of fetal monitors.
- Event marker for easy documentation of events and kick counts.

- 12-hours memory for fetal traces.
- Internal battery power or AC power from external power supply.
- 6-hours (approx.) battery back-up operation, rechargeable during normal monitoring.
- Download capability to transmit traces stored in its memory to a PC or a Philips OB TraceVue surveillance and alerting system.
- Online transmission to a monitoring system such as OB **TraceVue**.
- Easily connects to off-the-shelf printer for documentation.

Description

FM-2 is a fetal monitor for non invasively measuring, and showing maternal uterine contractions and the fetal heart rate as a graphic display, and optionally on a strip chart recorder, printer or OB **TraceVue** system. The data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy nonstress test (NST).

This portable fetal monitor offers a solution for antepartum screening in the private doctor's office, outpatient clinics, and for remote applications such as traveling nurses visiting patient's homes, or for clinics in rural areas seeking remote consultation.

It is intended for use only by trained medical personnel located in hospitals, clinics, doctor's offices and in the patient's home or during transport under the direction of a licensed practitioner.





Alerting

The FHR alarming has configurable upper, lower and delay time alarm limits. Enabled alerts are both visible and audible. Alerting can be switched off.

Transducers

It uses the same transducers originally designed for high acuity care settings. Reliable, durable, water tight, and easy to clean they interface to all Series 50 fetal monitors.

Chart-Ready Documentation Using a Printer

Connects to an HP DeskJet printer, using standard printer paper. This gives an economical, chart-ready printout that can be stored in the patient record. It can be faxed easily for remote consultations. See the Printer Specifications for a list of supported printers.

Interface to OB TraceVue Surveillance and Alerting System

The monitor can transmit patient data via a modem to an OB **TraceVue** system. It can also connect directly to an OB **TraceVue** system for realtime, online monitoring.

Traditional Documentation Using the Recorder

You can share the optional external recorder between several FM-2 monitors, to document stored fetal traces as traditional paper documentation. Also, the recorder has a real-time fetal trace output when connected continuously to the FM-2 monitor.

Monitor Connectors and Interfaces

- RS232 serial port (9pin male) for modem, PC, cellular phone.
- Standard parallel printer port for connecting printer or recorder.
- Connector for remote event marker cable.
- 3 transducer sockets (2 US, 1 Toco).
- Power inlet for power supply.

Self Test

The monitor automatically performs a self test when the power is switched on.

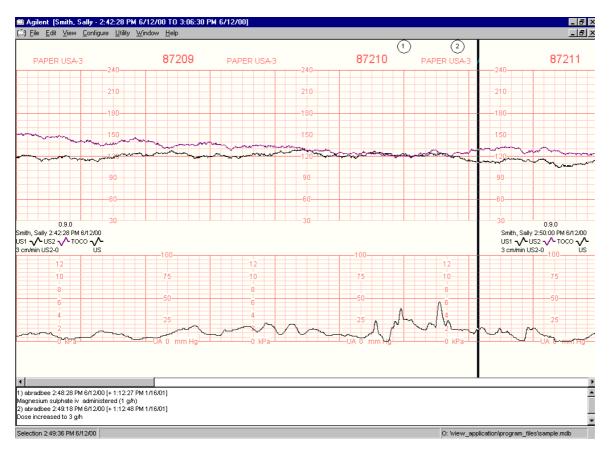
Mounting

The monitor can be mounted on a wallstand or a rollstand.

Interface to PC

FM-2 viewer is an optional, customer installable, PC software utility running on an IBM-compatible PC. See theFM-2 Viewer Specifications for system requirements.

It acts as a receiver and electronic storage medium. It accepts fetal traces downloaded from the monitor, either directly, or via a modem. It also offers the possibility to browse, annotate and print complete, or partial patient records. Data can be stored electronically on the PC or other storage media.



Monitoring Accessories

Standard Accessories and Supplies

These are included with the monitor

- 1 x Doppler Ultrasound FHR Transducer-M1356A¹
- 1 x External TOCO Transducer M1355A
- 1 x Remote Event Marker 15249A
- 2 x Reusable Abdominal Belts M1562A
- 1 pack of three transducer knob adapters -M1356-43203
- 1x 250ml ultrasound gel
- · User's Guide
- Pocket Guide to Fetal Monitoring and Assessment by Susan Martin Tucker (English language shipments only). ISBN 0-323-00884-4, 4th edition
- Service Guide

Additional Supplies and Accessories

These are not included with the monitor, but can be purchased separately.

- M1356A Second Doppler Ultrasound FHR Transducer for twins monitoring.
- M3919A Canvas Tote Bag with room for monitor plus accessories.
- M1569A Belt Fastening Button Pack of 10.
- M2208A 100 Disposable Abdominal Belts
 1.3m long, 50mm wide (52" long, 2" wide). 1 box of 50 blue and 50 pink.
- 40483A Ultrasound Transmission Gel 12 x 250 ml bottles, shelf life 24 months maximum, 6 months minimum.
- 40483A 5 Liter Refill Container shelf life 24 months maximum, 6 months minimum.
- M1910A Paper
 Case of 40 packs thermal recorder paper, 0-100 mmHg IUP scale, 30-240 FHR scale, 1 min (3cm) highlights. Orange (USA).
- M1911A Paper
 Case of 40 packs thermal recorder paper, 0-100 mmHg IUP scale, plus 0-13 kPa scale, 50-210 FHR scale, no highlighted 3 cm lines. Green (International).

M1913A - Paper
 Case of 40 packs thermal recorder paper, 0-100 mmHg IUP scale, 50-210 FHR scale, 1 min (3cm) highlighted lines. Green. Not available in Europe.

Associated Products

External Recorder (M2925A)

The recorder is an external device for printing stored fetal traces, or realtime fetal trace output. It connects to the FM-2 via a standard (IEEE 1284 compliant)) printer cable.

FM-2 Viewer Utility Software (M2926A)

The monitor can send data to an IBM-compatible PC running Microsoft NT4 or 98.

See the specifications section of this data sheet for system requirements.

Mounting (M3904A and M3909A)

- M3904A GCX Wallmounting.
- M3909A GCX Rollstand

^{1.} The monitor has twins capability built in. To monitor twins you require an additional ultrasound transducer. Purchase additional M1356A.

Specifications

Monitor (M2922A)

Federal Law restricts this device to use by or on the order of a physician.¹

Standards Compliance

The FM-2 Portable Antepartum Fetal Monitor complies with the requirements of the Medical Device Directive 93/42/EEC and the following safety standards:

- EN60601-1/IEC60601-1, EN60601-1-1, EN60101-2-37
- IEC 1157
- IEC 60601-1
- UL2601-1
- CAN/CSA C22.2#601.1-M90

Class II equipment, double insulated Continuous operation

Parameter	Input Connector	Resulting Isolation		
US	BF	BF		
Тосо	BF	BF		

Electromagnetic Compatibility

Complies with EN60601-1-2

Environmental

Operating Temp: -10°C to 45°C

 $(50^{\circ} \text{F to } 110^{\circ} \text{F})$

-20°C to 60°C Storage Temp:

(-29°F to 175°F)

Relative Humidity: 20% to 90% non

condensing

0-3048m (10,000 ft) Altitude:

Dimensions

Height: 15.24 cm (6.0 inches) Width: 26.4 cm (10.4 inches) 13.7 cm (5.4 inches) Depth: Weight: 2.27 kg (5lb)

Power - Battery

Lead acid, rechargeable. Type: Operation: minimum 2-hours fully

charged at 10°C, longer

at higher temperature. Maximum 14 hours full Recharge during monitoring: recharge during monitor-

ing (typical 11 hours).

Recharge without

Maximum 8 hours to monitoring: full recharge when no

monitoring occurs (typical

4.75 hours).

Low power warning: Approximately 30 minutes

at 25°C.

Power - External Power Supply

110-120V~, 50-60Hz, **AC-powered**

> 0.15Aor

220-240V~, 50-60Hz,

0.08A

Display

Backlight: Cold cathode fluorescent

Active area: 3.78" x 2.83"

(320 x 240 dots)

Resolution: 85 dots per inch

Contrast: 10:1

Ultrasound

< 4mW I_{sata}:

BPM range:

Paper scale: USA paper: 30-240 BPM,

International Paper: 50-210

BPM.

Ultrasound

processing range: 50-240 BPM. ±1% ±1 BPM. Accuracy:

Leakage current: ≤10 µ A @ 264 VAC applied

to transducer.

Isolation: >4 kV RMS, Type BF

applied part.

Toco

0-100 relative units Range:

Resolution: 1 count

Accuracy: $\pm 1\% \pm 1$ relative unit Leakage:

 $\leq 10 \,\mu\,A$ @ 264 VAC applied

to transducer

Isolation: >4 kV RMS, Type BF

applied part

Transducers

Doppler Ultrasound FHR (M1356A)

Weight: 185 g (6.5 oz) Cable length: 2.5m (8ft 2in) Diameter: 75mm (2.95in)

Latex free

External Toco (M1355A)

Transducer Weight: 180 g (6.3 oz) Cable length: 2.5m (8ft 2in) Diameter: 75mm (2.95in)

Latex free

Remote Event Marker (15249A)

Length: 2.8m (9ft 2in)

Weight 75g (2.65oz)

Latex free

Reusable Abdominal Belt (M1562A)

Length: 1.3m (52in) Width: 50mm (2in)

With button holes, and pre-attached buttons. Can

be further cut. Contains latex.

FM-2 Viewer Utility Software (M2926A)

Windows operating system-based utility software. Supplied on CD-ROM, together with operating instructions, license and 3m PC connection cable.

System requirements:

• IBM-compatible PC (200MHz Pentium or equivalent)

• Standard VGA graphics adapter with 8MB memory

· CD-ROM drive

• 60 MB (minimum) available space on hard drive

• Windows 98, or NT (with service pack 6a) operating system

Microsoft®, and Windows® are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries.

The FM-2 viewer utility software complies with the requirements of the Medical Device Directive 93/42/EEC.

Federal Law restricts this device to use by or on the order of a physician.

Printers

Supported printers are:

• HP DeskJet 990Cxi

• HP DeskJet 980Cxi

HP DeskJet 960c

• HP DeskJet 840c

• HP DeskJet 640c

• HP DeskJet 350

• HP Photosmart 1215

This list will be updated periodically. Contact Philips Medical sales for details about currently supported printers.

Recorder (M2925A)

Dimensions

Height: 12.5 cm (4.9 inches)

Width: 23.4cm (9.2 inches)
Depth: 26.2 cm (10.3 inches)
Weight: 3.54 kg (7lb 13oz)

Standards Compliance

Safety

- Complies with EN60601-1, EN60601-1-1

- Class I equipment, requires 3-prong outlet with

protective earth Continuous operation

Electromagnetic Compatibility

Complies with EN60601-1-2

Power

AC-powered 110-120V~, 50-60Hz,

0.15A

or

220-240V~, 50-60Hz,

0.08A

Consumption: 20 watts maximum at

normal supply voltage

Environmental

Operating Temp: -10°C to 45°C

 $(50^{\circ}\text{F to } 110^{\circ}\text{F})$

Storage Temp: -20°C to 60°C

 $(-29^{\circ}\text{F to }175^{\circ}\text{F})$

Relative Humidity: 20 to 90% non condensing

Altitude: 0-3048m (10,000ft)

Recorder Paper (Thermal)

Style: Z-fold Pack size: 150 pages

End-of-pack: Mark along paper edge,

stop sign on last page

Loading: Front door, drop-in, self

aligning

Paper detectors: Paper out, and recorder

loading door open

Paper speeds: Normal (1, 2, and 3 cm/

min $\pm 1\%$) and batch print (average 25 cm/min)

Paper tracking $\pm 1\%$ (exclusive of paper

accuracy: accuracy)

M1910A: 30-240 FHR range, orange (Canada and USA) grid, no kPa scale, 3cm

highlighted lines.

M1911A: 50-210 FHR range, green

(International) grid, kPa scale, no

highlighted lines.

M1913A/J: 50-210 FHR range, green (Japan) grid, no kPa scale, 3 cm

highlighted lines.

capabilities of all fetal monitors to help you choose the monitor that is right for your needs.

Feature			42	P-2	X &	MO ^a
Table legend: Standard O Optional			Series 50A (M1351A)	ies 50 I И1353₽	ies 50 X	Series 50 XMO ^a (M1350C)
— Unavailable			SE	Ser (I	Ser (I	Serie (I
Designed for portability/transpo	rt	•	_	_	_	_
Integrated fetal trace display		•	_	_	_	-
On screen NST assessment aid			_	_	_	_
Battery operation and AC operation from power supply			_	_	_	_
Off the shelf printer interface			_	_	_	-
PC utility software			_	_	_	_
External recorder			_	_	_	_
Integrated recorder		_	•	•	•	•
Fetal trace data storage (12 hou	rs)	•	_	_	_	_
Transmission to obstetrical surveillance system (for example OB TraceVue) via phone line			0	_	_	_
Twins heart rate separation		•	•	•	•	•
Direct system interface to obstetrical overview system such as OB TraceVue			•	•	•	•
Watertight, easy to clean transd	ucers	•	•	•	•	•
Indication when two channels record the same heart rate (Cross Channel Verification - CCV)			•	•	•	•
Indication when you accidentally record maternal SpO ₂ (Cross Channel Verification plus - CCV+)			_	_	_	•
Performance PLUS! technology to ensure continuous, accurate and high-quality ultrasound traces			•	•	•	•
Precision signal track and hold to reduce artifacts and increase sensitivity			•	•	•	•
Interface to external fetal pulse	oximeter (FSpO ₂)	_	0	0	0	_
Gross fetal body movement recording (fetal movement profile - FMP)			0	0	•	•
External fetal measurements	Single US FHR	•	•	•	•	•
	Twin US FHR	•	0	•	•	•
	Тосо	•	•	•	•	•
Internal fetal measurements	DECG	_	_	•	•	•
	IUP/TTUIP	_	_	•	•	•
	Fetal SpO ₂ (FSpO ₂)	_	_	_	_	•
Integrated maternal	NIBP and SpO ₂	_	_	_	•	•
measurements	MECG	_	_	•	•	•
Interface to external maternal m	Interface to external maternal monitor			0	0	O b

a.Series 50 XMO not available in USA or Japan

b. When maternal parameters are not already integrated in the Series 50 XM/XMO monitor (that is, you have not ordered option A03)

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